CHAPTER 4
PERFORMANCE AGAINST OUTPUTS

OUTPUT 1.1: REGULATORY DECISIONS AND INFORMATION SUPPORTED BY EVIDENCE-BASED RISK ASSESSMENTS THAT ARE CONSISTENT WITH NATIONAL AND INTERNATIONAL STANDARDS

All manufacturers of pesticides and veterinary medicines must apply to the APVMA to register their products and obtain approval for product labels before the products can be supplied, sold, distributed or used in Australia.

Companies or individuals who hold a registration for a pesticide or veterinary medicine must also seek approval for any variation to the product, additional claims made about it, or changes to its label.

Registration is based on a rigorous and independent evaluation of scientific information about the safety and efficacy of a product. The APVMA grants registration if the evaluation of a product has shown that it is not likely to be harmful to target crops or animals, to users, consumers and the environment. The evaluation also has to demonstrate that the product is effective, suitably formulated and that its label contains adequate instructions. The APVMA must also assess whether using the product may unduly prejudice trade.

This careful evaluation ensures that the community and users of pesticides and veterinary medicines can be confident that the products are safe and effective when used according to label instructions.

The APVMA uses three key strategies to build stakeholder confidence in the assessment of pesticides and veterinary medicines:

Strategy 1: Evaluate and consider applications to approve active constituents, register chemicals, approve labels and provide regulatory consents, such as permits, following scientific evaluation.

Strategy 2: Engage stakeholders to improve awareness and inform policy development and to optimise the regulatory framework within which APVMA operates.

Strategy 3: Review registered chemicals on the basis of their risk.

Strategy 1: Evaluate and consider applications to approve active constituents, register chemicals, approve labels and provide regulatory consents, such as permits following scientific evaluation

The APVMA aims to complete all applications in the statutory timeframes set out in Schedule 6 of the Agricultural and Veterinary Chemicals Code Regulations 1995 (Agvet Code Regulations).

The statutory timeframe varies from three months for a simple variation to a currently registered product, to 15 months for a new product that uses a new active constituent (see Appendix B).

In the following pages, both elapsed time and the 'clock time' (the statutory timeframe) are reported:

- The 'elapsed time' is overall time taken for an application to be evaluated, determined and finalised. It is the sum of the time that the clock for the statutory timeframe is ON (action rests with the APVMA) plus the time that the clock is OFF (action rests with the applicant). It starts from the day the application is accepted to the day that it is granted, refused or withdrawn.
- The 'clock time' is the time the application is being processed by APVMA. It does not include the time an applicant may take to respond to an APVMA requirement for more information, provision of labels or when an application is suspended or deferred at the request of the applicant.

The elapsed time is always longer than clock time because of a 'stop clock' provision: the statutory clock is turned off while the applicant responds to APVMA requirements for information. The 'clock off' time can be short if the applicant is able to respond to the requirement quickly, but it could be long if the applicant decides to conduct new studies. The clock off time can also be long if the applicant and the APVMA have agreed to suspend or defer consideration of the application pending the finalisation of another, linked application or if applicants elect to submit certain parts of the dossier at a later time (this is called timeshift).

Reducing the elapsed time

Elapsed times and clock times for pesticide and veterinary application finalisations in 2008–09 are in Table 9 and Table 11. The APVMA has continued to work with industry to reduce the elapsed time for applications as part of the Elapsed Time Project, which is now into its third year.

As a result of this project, registration managers have addressed some key blockages, and this is expected to reduce the elapsed time of some applications. These relate particularly to delays associated with differences in the perceptions of industry and the APVMA about how applications should be processed. This is clearly a work in progress, but with careful management of relationships and pro-active decision making at particular stages in the evaluation process, continuous improvements can be expected throughout 2009–10.

Specific initiatives expected to improve the APVMA's performance in meeting statutory timeframes include:

- *Further use of 'timeshift' applications*: the timeshift process allows applicants to lodge an application even though all required data are not available. The APVMA can commence evaluation of data with longer timeframes (such as toxicological and environmental data) while other data requirements such as efficacy are still being generated to be provided at a later date. Although timeshift is being piloted, the APVMA plans to further refine and expand the use of timeshift applications during 2009–10 to allow greater flexibility for applicants and to reduce overall elapsed time.
- *Project management of large applications:* the APVMA encourages applicants of major new products to adopt a project management approach to improve certainty and predictability. The approach primarily involves applicants meeting with APVMA prior to lodging an application to clarify matters regarding data requirements and likely submission and assessment dates. The generated project plan allows both applicant and APVMA to track progress against agreed milestones.
- *The Registration Process: a* new MORAG chapter that describes the registration process, from pre-application meetings to finalisation, will be published during 2009–10. The chapter allows applicants to view the many steps and decisions through which applications must progress. The inclusion of process maps also clarifies how APVMA manages tracking 'clocks' to record compliance with statutory timeframes.
- *Accurate reporting of elapsed time:* the reporting of average elapsed time for all applications allows applicants to predict how long it is likely to take for an application to be finalised. During 2009–10, the APVMA will adjust its elapsed time reporting to separate applications for example as timeshift applications; applications with suspended consideration; the applications for which the applicant has volunteered new data after initial data have been evaluated completed; and international work share applications. Separation of elapsed time reporting of these applications will give a more accurate report and aid in predictability.
- *Continuous improvement of registration quality management system:* during 2009–10 the APVMA will be improving its internal registration processes to gain further efficiencies.

In 2008–09, the APVMA progressed an Australian National Audit Office (ANAO) recommendation to record defects associated with product applications. It will be further progressed in 2009–10, and it will allow the APVMA to better target guidance and education and to improve the quality of applications and thus timeframe to registration.

Pesticide product applications approved

The Pesticides Program received approximately the same number of applications in 2008–09 as in 2007–08 (Table 8). About five per cent fewer applications were carried over to 2008–09 than were carried over to 2007–08 (1149 compared with 1206). By the end of 2008–09, approximately six per cent more applications were still in progress at the end of the 2008–09 financial year than there were in the previous financial year (1219 in 2008–09 compared with 1149 in 2007–08).

Overall, finalisation rates for pesticide applications were similar to those in the previous financial year. The APVMA completed 85 per cent of applications within the statutory timeframe during 2008–09, which is comparable to the 83 per cent of applications finalised during 2007–08 (Table 9).

Applications that fall within the five- to nine-month timeframe, proportionally, have the longest elapsed times to finalisation. The elapsed timeframes are primarily a result of changes to the staffing levels of the chemistry team during the year and agreements to accept new data during the assessment of an application. Those application categories for which there are long elapsed timeframes continue to be addressed, namely through task-force approaches to reducing backlogs, as well as reviewing applications against which there has been little activity for a period of time. With the 13 to 15 month categories, finalisation of two long-standing applications (approximately 96 months elapsed time and 31 months clock-time) have impacted upon the statistics for this group; hence there is a significant increase in elapsed times compared with last year.

Table 8: Pesticide product applications for product registration or variation for 2008–09

APPLICATIONS	2008–09	2007–08	CHANGE FROM 2007–08 (%)
Commencing number of applications in progress	1149	1206	-4.7
Applications received	1583	1543	+2.6
Applications finalised	1513	1549	-2.3
Closing number of applications in progress	1219	1149	+6.1

Table 9: Pesticide product finalisations for 2008–09

CLASS OF APPLICATION	TOTAL FINALISED	NUMBER IN TIMEFRAME	% IN TIMEFRAME	AVERAGE CLOCK TIME TO FINALISE	AVERAGE ELAPSED TIME TO FINALISE (MONTHS)
Received before 1 July 2005	2	0	9%	30.8	95.7
Modular	2	2	100%	0.0	5.6
2 to 3 months	1043	988	95%	1.3	5.5
5 months	135	48	36%	6.9	16.2
6 to 8 months	46	19	41%	8.2	16.1
9 to 12 months	32	14	44%	10.8	22.2
13 to 15 months	10	3	30%	18.0	41.5
TOTALS	**1268**	**1074**	**85%**		

Note: Statistics include 245 applications received in screening that were either withdrawn by the applicant or considered as withdrawn in 2008–09. This means that, although the APVMA did not accept these applications for evaluation, it regards them as finalised.

New pesticide technology for Australian agriculture

The APVMA registered several pesticide products based on new active constituents during 2008–09. These new products are:

- a locally developed product based on plant extracts (including alpha-pinene, anisyl alcohol, butyl salicylate, D-Limonene, eucalyptol and phenylacetaldehyde), which acts as an insect attractant and is for the integrated management of *Heliocoverpa spp* in cotton, green beans and sweet corn (see A totally homegrown innovation)
- a new insecticide containing flubendiamide that provides a new tool for Australian horticultural industries to control various insect pests
- a new insecticide containing spinetoram for the control of codling moth, light brown apple moth and oriental fruit moth in pome and stone fruit
- an insecticide containing chlorantraniliprole for the control of Lepidopteran pests in vegetables and white grubs in turf
- a herbicide containing ethoxysulfuron that provides a new tool for the sugar cane industry to control Nut Grass *Cyperus rotundus*.

A totally homegrown innovation

It is rare when all research and development work for an agricultural chemical product— including the sourcing of the necessary funds—occurs exclusively within Australia. A new insect attractant for the management of *Heliocoverpa spp* is a recently registered product that belongs to this rare category.

According to CropLife International's estimates, it takes 8–10 years at an average cost of between $A225 million and $A270 million to develop a new agrochemical from the initial research undertaken to registration. Given that the development of a new agrochemical is such an enormous task, the registration of this new product is the final step of a remarkable achievement. The product is also a significant innovation in that it is the first registered moth attractant based on plant volatiles anywhere in the world.

International work sharing

During the 2008–09 year, the APVMA worked with several overseas regulatory agencies in joint reviews or work sharing for assessments of new pesticide active constituents. The APVMA progressed one joint pesticide review to its final stages, and began another three joint reviews of new active constituents and their formulated products (see 'International engagement' for more details, page 50). As a result of the experience with these joint reviews, the APVMA has introduced a pilot program that provides a planning approach to work with applicants to manage major applications intended for Australia only.

Veterinary medicine applications approved

The Veterinary Medicines Program received 8.7 per cent more applications in 2008–09 than in 2007–08, and it completed 0.6 per cent more—resulting in a greater number of applications in progress at the end of the year (see Table 10). Eighty-eight per cent of the veterinary medicine product applications were completed within the statutory timeframes. In contrast, 91 per cent of applications were completed in 2007–08 (Table 11).

During 2008–09, 63 applications screened during the year or previous years were either withdrawn by the applicant or treated by the APVMA as having been withdrawn. The APVMA rejected one application in screening. This means that the APVMA did not accept this application for evaluation. The average elapsed time increased from 2007–08 to 2008-09 (it is these averages – for all applications in a class – that are shown in Table 11). Average elapsed time has increased largely due to issues with staffing in the Chemistry team during the year. The establishment of the pharmaceutical chemistry capability within Veterinary Medicines will see elapsed time reduce in 2009–10.

There are some difficulties in measuring elapsed time. For example, when a long-standing application is finalised, the elapsed time for that application becomes part of the calculation, which can result in an overall increase in the average elapsed time. This can result in the elapsed time being artificially high. Those applications that are project-managed, including timeshift applications, also form part of the elapsed time calculation. The APVMA recognises the limitations of the current method of measuring elapsed time and has measures underway to bring a greater level of sophistication to the reporting of elapsed time in 2009–10.

Table 10: Veterinary medicine product applications for product registration or variation for 2008–09

APPLICATIONS	2008–09	2007–08	CHANGE FROM 2007–08 (%)
Commencing number of applications in progress	738	691	+6.8
Applications received	911	838	+8.7
Applications finalised	744	711	+0.6
Closing number of applications in progress	846	738	+14.6

Table 11: Veterinary medicine finalisations for 2008–09

CLASS OF APPLICATION	TOTAL FINALISED	NUMBER IN TIMEFRAME	% IN TIMEFRAME	AVERAGE CLOCK TIME TO FINALISE	AVERAGE ELAPSED TIME TO FINALISE (MONTHS)
Received before 1 July 2005	1	1	100%	0.7	53
2 to 3 month	547	534	98%	0.9	7.3
5 month	153	95	62%	4.9	16.4
6 to 8 month	26	14	54%	8.6	21.1
9 to 12 month	12	6	50%	11.2	38.0
13 to 15 month	5	2	40%	18.0	37.5
TOTALS	**744**	**652**	**87.6**		

New products for the animal health industry

During 2008–09, the Veterinary Medicines Program registered two new antibiotics containing cefovecin and ibafloxacin. Four new veterinary drugs for use in treating dogs were registered. These drugs contained mitratapide (controls obesity), maropitant (controls vomiting), fluoxetine (to treat separation anxiety) and trilostane (for Cushing's syndrome). A new combination of clorsulon, ivermectin and nitroxynil was added to the pool of anthelmintics. The APVMA registered the first spinosad chewable tablets for controlling flea infestations on dogs.

Timeframe performance

The APVMA's legislative requirement is to determine all applications within the statutory timeframe—this is called the 'timeframe performance'. During 2008–09, the timeframe performance of the Pesticides Program was 85 per cent and the Veterinary Medicines Program 88 per cent.

The performance is less than 100 per cent because of the priority the APVMA places on maintaining consistently high standards of rigour, quality control and quality of decisions, despite the impact of staff turnover on the APVMA's capacity to address the variable workload and increased administrative burden. The APVMA is addressing these issues by concentrating effort around core activities and progressing several operational initiatives to improve workflow management.

Registration statistics can be found on the APVMA's website at <http://www.apvma.gov.au/perfreporting/subpage_reporting.shtml>

Permits and Minor Uses

Pesticides

During 2008–09, 512 pesticide permits were finalised, of which 384 (75 per cent) were completed within the statutory timeframe. Approximately 73 per cent of finalised applications were for Minor Uses, 9 per cent were for emergency uses and 18 per cent were for research purposes.

During the year, further progress was made in registering more Minor Uses, mainly by moving Minor Uses from current permits to product labels. Applications considered and approved for the registration of Minor Uses included:

- the use of a product containing copper in spring onions and shallots (PER6930), leeks, cucumber, radish, swedes and turnips (PER9916), ornamentals (PER7734); the registration also incorporated extensions to Brassica vegetables and Brassica leafy vegetables
- the use of a product containing fipronil in asparagus (PER9425), sweet potato (PER9063), forestry (PER9817), ginger (PER6769), swedes and turnips (PER10427)
- the use of a product containing 2,4-D to control lucerne at the commencement of fallow (PER5410)
- various registered products containing tebuconazole in lettuce (PER9127).

To enhance the quality of Minor Use permit applications, the APVMA hosted a full-day workshop with 12 consultants who are responsible for data generation and submission of Minor Use permit applications on behalf of horticultural industries. Additionally, the APVMA continued to meet with a wide range of stakeholders to discuss Minor Use needs and regulatory requirements. These groups included the Grains Research and Development Corporation, Cotton Research and Development Corporation, Rural Industries Research and Development Corporation, Horticulture Australia Limited, NSW Farmers Association, Australian Oilseeds Federation, National Weeds Committee representatives, SmartTrain, Australian Olive Association, and the turf industry.

Queensland Board Approvals

The APVMA continued finalising the review of existing state-based permits issued before the commencement of the National Registration Scheme (pre-March 1995). This included cancellation of 265 Queensland Board Approvals. The APVMA will assign cancellation dates for the remaining approvals by the end of 2009, with anticipated dates to be extended over a number of years. The APVMA will require industry to formally apply for Minor Use permits for required uses.

Emergency use permits

Emergency use permits are issued by the APVMA to address a diverse range of needs, such as managing biosecurity risks, managing unforeseen pest and disease pressures in agricultural crops, meeting market access requirements, and for protecting the environment. Permits issued during 2008–09 included:

- control of Asian honeybees as a potential varroa mite host
- control of Branched Broomrape (*Orobanche ramose*) host plants
- maldison for fruit fly baiting in grapes and passionfruit
- several integrated pest management selected insecticides in culinary herbs
- various fungicides for control of botrytis in eggplant
- control of cactorum root and crown rot in strawberries
- control of citrus leaf spot, which is a new exotic disease
- control of aphids in canola
- control of rodents in teak and coffee plantations
- control of *Fusarium* head blight in wheat
- control of rust in soybeans
- control of water hyacinth by aerial application
- control of powdery mildew in sunflowers
- control of Two-spotted Mite (*Tetranychus urticae*) in watermelons
- various insecticides for the control of Yellow Crazy Ant (*Anoplolepis gracilipes*)
- destruction of unwanted grapevines to prevent spread of *Phylloxera*
- control of teak defoliator in teak plantations
- maintenance of various permits for the control of Australian Plague Locust (*Chortoicetes terminifera*) and Red Imported Fire Ant (*Solenopsis invicta*).

International engagement and Minor Uses

The APVMA maintained its active involvement in international activities associated with Minor Uses. Refer to 'International engagement' (page 50) for further detail.

Veterinary medicines

During 2008–09, the Veterinary Medicines Program finalised 169 Minor Use permit applications, of which 157 (93 per cent) were finalised within the statutory timeframe.

Minor Use permits were granted to producers in the aquaculture industry to administer trichlorfon, potassium permanganate and copper sulphate to Silver Perch (*Bidyanus bidyanus*), and methyltestosterone to salmonids. Permits were re-issued for doxycycline use in replacement layer pullets, and for rifampicin and erythromycin use in foals. A permit was issued for the use of diazinon for cage dipping of sheep so that industry could generate occupational health and safety exposure data to support this use pattern. A permit was also issued for the use of tramadol for pain relief in dogs and cats, and methocarbamol for relaxing muscles of dogs, cats and horses.

Chemistry and residues assessments

When evaluating applications to either register products or grant permit approvals, the APVMA must be satisfied that the constituents and manufacturing process for a product are appropriate and that products can be used safely without concern about potential residues in food. A dietary exposure assessment is conducted to establish if the use of a product on food crops or animals will be acceptable against relevant health standards, namely the Acceptable Daily Intake and the Acute Reference Dose. The APVMA ensures that dietary exposure, assessed using internationally recognised methods, iss acceptable against the established health standards before registering a product or granting a permit.

Chemistry

Staff movements to other agencies or other areas within the APVMA caused a reduction in output, which led to a significant backlog in chemistry evaluations. The restructure of the team and a recruitment drive saw a steady increase of output: 15 evaluations were completed in October 2008, and this increased to 28 evaluations being completed in February 2009. From March 2009 to June 2009 alone, 163 evaluations were completed, which was more than the 102 applications that were referred to the Chemistry team for evaluation in the same period.

The APVMA has reduced the substantial backlog within the Chemistry team using a 'Tiger Team' approach—this involves grouping specific application categories together and evaluating them sequentially. Shelf-life extensions were collated and addressed first before moving onto Category 5 and 6 applications, then Category 10 applications, and currently efforts are focused on finalising Category 14 applications (see Appendix B for a description of the categories). This was achieved through dedicated staff effort and contribution, and overtime.

The APVMA also allowed applicants with multiple applications awaiting chemistry evaluation to prioritise within their own list of outstanding evaluations amongst the overall list of applications. This reduced the impact on applicants with delays associated with the substantial chemistry backlog.

The APVMA has since decided to establish a separate pharmaceutical chemistry capacity in the Veterinary Medicines Program. This occurred in late June 2009 with the team becoming operational in July 2009.

Residues

The APVMA evaluated residue data for 59 applications for product registration, 150 applications for permits and 14 applications for emergency permits. Collectively, these produced 263 amendments to the APVMA's maximum residue limits (MRL) standard.

The Japanese Positive List is a five-year project that was started in 2006–07 through DAFF with support from relevant industry organisations. The aim of the project is to provide information to the Japanese Ministry of Health, Labour and Welfare to support the establishment of MRLs in Japan based on Australian use patterns and registrations. In 2008–09, the APVMA provided information through this project to support MRLs for 49 pesticides and nine veterinary medicines.

The Taiwanese Bureau of Food Safety asked for information from Australia to help establish MRLs for pesticides in crop commodities. The APVMA provided information on 21 pesticides to assist with this process.

In 2008–09, the APVMA continued to work with Food Standards Australia New Zealand, to streamline the transfer of MRLs into the Food Standards Code.

Communication of trade advice

In 2008–09, the APVMA continued its initiatives to enhance communication of trade risk advice. The APVMA has been a participant with DAFF in consultative meetings addressing the issue of mandatory display of trade advice on product labels. APVMA has continued to develop statistical methods to assist in the determination of export slaughter intervals for veterinary medicines.

A key objective of trade evaluations is to ensure that Australian trade to other countries will not be unduly prejudiced as a result of product registration. Trade advice on labels is an essential part of the whole-of-food-chain quality assurance process. It enables the livestock producer to accurately complete the National Vendor Declaration under Meat and Livestock Australia's Livestock Production Assurance Scheme. The APVMA sets export slaughter intervals with the registrant and the relevant producer industry.

During 2008–09, the APVMA developed a market list to establish export slaughter intervals. Government and industry stakeholders were consulted, and the list is to provide greater transparency in the selection of markets used to derive appropriate intervals.

Quality of regulatory science

The APVMA enhances the quality of its regulatory science through its two Principal Scientists and by engaging scientists external to the APVMA: Science Fellows and Visiting Scientists.

The two Principal Scientists—Dr David Loschke, Principal Scientist for Agricultural Chemicals, and Dr Phil Reeves, Principal Scientist for Residues and Veterinary Medicines—carry overall responsibility for improving the quality of scientific work in the APVMA, increasing domestic and international awareness of the APVMA's scientific strength, and effectively managing science-related issues and projects in the APVMA. Their achievements in 2008–09 are listed in Table 12.

The Veterinary Medicines Science Fellows form a panel of eminent national and international scientists to enhance the quality of regulatory science and build public confidence in the APVMA. The Science Fellows were until recently the sole providers of high-level external scientific expertise to the APVMA. A 2008–09 review of the program found that this was not sustainable because it placed considerable demands on them. As a result, a new model was established to involve two groups of external experts: Science Fellows and Visiting Scientists. The two groups perform different, but complementary, functions.

The current Science Fellows for the Veterinary Medicines and the Pesticides programs and their fields of expertise are shown in Table 13. Science Fellows provide high-level independent advice on complex and contentious regulatory issues; assist in the development of regulatory science policy; provide advice in relation to staff training; and speak at APVMA Science Fellows symposia.

The Veterinary Medicines Science Fellows' work is also now supported by a Veterinary Medicines Expert Advisory Panel (VMEAP), established during 2008–09. The VMEAP complements the regulatory science activities of the Veterinary Medicines Program and provides a useful consultative mechanism. The VMEAP meets two or three times annually, and Science Fellows with expertise relevant to a matter under consideration attend. The inaugural meeting of the VMEAP in April 2009 was attended by Science Fellows Professor Mary Barton and Professor Glenn Browning as it addressed regulatory issues relating to antibiotics and veterinary vaccines.

Visiting Scientists are responsible for the delivery of training to staff. Staff can also access them for advice on scientific risk assessments when processing applications. All training materials presented by Visiting Scientists are placed in an electronic repository that can be accessed online by evaluators.

The inaugural APVMA Visiting Scientist is Dr Michael Chambers, who was appointed in June 2009. He presented a training workshop on clinical trials for staff of the Veterinary Medicines Program. Additional Visiting Scientists with expertise in other scientific fields will be appointed, and their contact details will be added to a register dedicated to the purpose.

Table 12: Achievements of the APVMA Principal Scientists in 2008–09

OBJECTIVE	PERFORMANCE
Improve the quality of scientific work in the APVMA	Spray drift concerns were a focus of activities in 2008–09. Achievements by Principal Scientist Dr Loschke included: • completing and finalising the *APVMA Operating Principles In Relation to Spray Drift Risk* along with its accompanying regulatory impact statement • providing special training sessions and workshops in spray drift modelling and risk assessment for the chemical risk assessment staff within the Department of the Environment, Water, Heritage and the Arts • providing training sessions for APVMA staff in how to implement the new refinements to the APVMA's spray drift risk assessment methods.

OBJECTIVE	PERFORMANCE
Increase domestic and international awareness of the APVMA's scientific strength	Both Principal Scientists are actively engaged with the Australian and international scientific communities. Dr Loschke: • gave overseas presentations to an OECD meeting on pesticide risk reduction and the California Environmental Protection Agency on the APVMA's risk management for spray drift • took part in forming the new OECD Network of Experts on Spray Drift and the new OECD spray drift information website. • was invited to give presentations on chemical risk assessment to many conferences in Australia in 2008–09, including Land & Water Australia's Great Barrier Reef Conference, and conferences of National Farmers Federation and the Aerial Agriculture Association of Australia. Dr Reeves: • participated in the 70th Meeting of the Joint FAO/WHO Expert Committee on Food Additives and completed residue assessments of triclabendazole and tylosin; the monographs of which have been published by the FAO • had a book chapter on drug residues accepted for publication in 2009 • participated on the VICH Expert Working Group on metabolism and residue kinetics as the Australia–New Zealand representative, from which four draft guidelines on data requirements are soon to be distributed. • was a Guest Lecturer at the University of Sydney, Charles Sturt University and Monash University • served on two editorial boards. In July 2008, Dr Reeves stepped down from the Board of Examiners of the Australian College of Veterinary Scientists after eight years of service.
Effectively manage science-related issues and projects in the APVMA	As part of their ongoing engagement in science problems for registration and review: • Dr Loschke developed further methods and standard approaches for risk assessment in 2008–09. The most significant of these were a suite of standard spray drift risk assessment scenarios, standardised no-spray zones, and extension and refinement of a new bystander risk assessment model for spray drift. • Dr Reeves reviewed several complex and contentious evaluation reports, providing advice on them to program managers and the CEO. Since June 2009 he has also been analysing the training needs of evaluators in the Veterinary Medicines Program.

Notes: FAO = Food and Agriculture Organization; WHO = World Health Organization; VICH = The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products

Table 13: The APVMA's Science Fellows as at 30 June 2009

SCIENCE FELLOWS	EXPERTISE
PESTICIDES PROGRAM	
Dr Andrew Hewitt	Spray Drift Science & Control
Dr Rai Kookana	Environmental Toxicology
Professor Stephen Powles	Herbicide Resistance Mechanisms
Professor Brian Priestly	Toxicology of Pesticides
Professor Bernard Stewart	Carcinogenic Substances
VETERINARY MEDICINES	
Dr Dieter Arnold	Residues of Veterinary Drugs in Foods
Professor Mary Barton	Antibiotics and Antibiotic Resistance
Professor Glenn Browning	Veterinary Vaccinology
Professor Colin Chapman	Pharmaceutical Sciences and Veterinary Pharmacology
Emeritus Professor Jock McLean	Toxicology of Veterinary Drugs
Professor Terry O'Neill	Statistics
Professor Nicholas Sangster	Veterinary Parasitology

APVMA Science Seminars

The APVMA science seminar series showcases the vast agricultural and veterinary scientific expertise of APVMA professional staff. The series educates staff, contributing to their continuous learning and development. It also develops internal relationships that acknowledge existing APVMA expertise. The science seminar series will continue in 2009–10, presenting topics on diverse fields: from pesticide formulations to geographical information systems and spray droplet behaviour.

Four APVMA staff presented seminars on the following topics in 2008–09:

- bee keeping in Australia, bee physiology and hive anatomy
- WHO/FAO Joint Meeting on Pesticides Residues
- enzymatic bioremediation technology: enzymes to clean up pesticide contamination
- fumigation techniques.

Nanotechnology

The APVMA continues to prepare for regulating the use of nanotechnology in pesticides and veterinary medicines as part of a whole-of-government approach to the issue. Principal Scientist Dr Reeves led activities in this area in 2008–09, in collaboration with Dr Jamie Nicholls in his role as Regulatory Strategy Project Officer up to the end of 2008. This included a review to ensure the framework is appropriate to regulate products of nanotechnology.

The Industry Liaison Committee, the Registration Liaison Committee and the Community Consultative Committee were provided with papers on nanotechnology, and a position paper was published on the APVMA website.

In August 2008, the APVMA hosted a nanotechnology training session at which APVMA Science Fellow Professor Brian Priestly spoke on the fundamental principles and applications of nanotechnology. Professor Priestly was ably supported Dr Nick Fletcher of the Therapeutic Goods Administration and Peter Wallner of Food Standards Australia New Zealand, who addressed the applications of nanotechnology in therapeutic goods and food, respectively. In May 2009, scientific staff from the APVMA attended a nanotechnology training forum hosted by the Therapeutic Goods Administration. Both of these training events were very well received.

To assist with its regulatory preparedness, a notice of 'Call for Information' was published in the APVMA Gazette to gain a better appreciation of the kinds of nanomaterials that will be used in Australian agriculture in the short-term. The nil response to the notice suggested that APVMA is unlikely to receive applications for nanoscale pesticides and veterinary medicines in the very short-term.

The APVMA Science Fellows Symposium 2009

In March 2009, Dr Loschke hosted the APVMA Science Fellows Symposium. This year it featured the Pesticides Program and was devoted to the topic of pesticide risk assessment. The five current Science Fellows for the Pesticide Program each addressed that theme with the following presentations from their fields of expertise.

- Dr Andrew Hewitt: The science of spray drift management
- Dr Rai Kookana: Minimising offsite migration of pesticides and ecological risk reduction
- Prof Stephen Powles: Herbicide resistance and its management in Australia
- Prof Brian Priestly: Toxicology of chemical mixtures — are we any closer to a rational risk assessment methodology?
- Prof Bernard Stewart: Environmental carcinogenic risk appraisal and its impact on the community

The Symposium, held at the CSIRO Discovery Centre in Canberra, was very well-received by a large audience. The APVMA received many compliments on the quality of the speakers and the relevance of their topics.

Advice from external agencies

In evaluating applications for registration, the APVMA receives advice from various Australian Government and state and territory government agencies on human health (toxicology and occupational health and safety), the environment, efficacy, target animal and crop safety, and genetically modified products and organisms.

Formal service level agreements exist between the APVMA and the agencies to ensure that advice provided is cost-effective, accountable and has relevant performance measures. Services include assessments for registration and permit applications, assessments of chemicals under review and other professional advice. Throughout 2008–09, the APVMA maintained and revised its service level agreements with the Department of the Environment, Water, Heritage and the Arts (DEWHA) and the Office of Chemical Safety and Environmental Health (OCSEH) within the Office of Health Protection of the Department of Health and Ageing. DEWHA delivered 81 per cent of application assessments within timeframe and the OCSEH 73 per cent.

The APVMA maintained its Memorandum of Understanding with the Office of the Gene Technology Regulator in 2008–09. That Office advises the APVMA on the impact of pesticides and veterinary medicines on genetically modified organisms and on genetically modified organisms that are part of pesticide and veterinary medicine products. The APVMA also provides comment on relevant draft risk assessments prepared by the Office of the Gene Technology Regulator.

The APVMA has maintained and revised the *Efficacy and Target Animal/Crop Safety Reviewer's Manual* to assist reviewers and applicants in their understanding of assessment of efficacy and target animal and crop safety.

Deeds of standing offer

The APVMA supplements the scientific advice received from various Australian Government and state and territory government agencies by engaging external scientific service providers. The external scientific service providers are selected using a series of Australian Government policies that relate to the expenditure of Commonwealth funds, including the 2005 Commonwealth Procurement Guidelines. These guidelines require the APVMA to ensure that expenditure delivers value for money, encourages competition and is an efficient, effective and ethical use of resources.

The APVMA has implemented the *Manual for External Scientific Reviewers* to assist external scientific reviewers in their understanding of assessment relating to review services, as well as registration applications relating to toxicology, occupational health and safety and efficacy.

Strategy 2: Engage stakeholders to improve awareness, inform policy development and to optimise the regulatory framework within which APVMA operates

Engagement with stakeholders is a crucial part of the APVMA activity. It serves two key functions. Firstly, it provides a mechanism that allows the APVMA to inform stakeholders about the organisation, its role and activities. Secondly, the process provides the APVMA with information about stakeholder expectations, which it can use to improve organisational performance and to inform policy development.

Stakeholder consultative committees

The APVMA has continued to widely consult on regulatory matters. It supported a number of formal consultative committees that provide advice to the APVMA and serve as mechanisms for the communication of information to stakeholder groups. The committees comprise the Community Consultative Committee, the Industry Liaison Committee, the Industry Technical Committee, the Registration Liaison Committee and the Manufacturing Licensing Scheme Industry Liaison Committee. Details of issues considered by the consultative committees are reported at Appendix C. The committees are supported by the APVMA's secretariat unit, which is based in Public Affairs.

Beyond these formal committees, the APVMA provided information on the outcomes of regulatory decisions and processes through the monthly APVMA Gazette, the fortnightly Regulatory Update, media statements, the website, various special purpose publications, presentations and meetings.

There were two significant communication initiatives during the year. In the first of these, the APVMA developed a web-based tool to help consumers understand the meaning of various terms that are found on the labels of home and garden pesticide and herbicide products. This web based tool was an initiative of the Community Consultative Committee. Using this tool, consumers can choose products that best suit them on the basis of the type of risk they wish to accept.

The second initiative was the Science Fellows Symposium held in Canberra on 30 March 2009. At this well-attended event, five eminent Australian scientists gave excellent presentations on topical issues that included managing spray drift, assessing chemical mixtures and herbicide resistance.

Stakeholder engagement strategy

Work on the APVMA's current stakeholder engagement strategy started in 2007–08, but it was halted in 2009 while resources were directed to engaging and consulting stakeholders on the review of the authority's cost recovery arrangements. The APVMA actively sought and considered the views of stakeholders and provided responses to all stakeholder feedback. Work on the development of the strategy will recommence in 2009–10 and pick up relevant initiatives flagged in the *Operational Plan 2008–2009*, such as the development of a stakeholder feedback database and enhanced feedback management processes.

Strategic issues management framework

The APVMA made steady progress in developing its strategic issues management framework. In December 2008, senior staff completed their training on international best practice in issue management. The identification of issues is now a standard agenda item for consultative committees, and executive management considers emerging issues on a weekly basis. This work will continue in 2009–10 by, for

example, convening an internal group to systematically screen emerging issues. The APVMA will also formally consider management strategies for specific issues as they arise at executive meetings.

Development of new website

Major steps were taken in the development of a new APVMA website during the year. The site has been redesigned and existing content reviewed to ensure its currency and accessibility. The new website, currently awaiting final approval, incorporates many technical enhancements. Preliminary feedback already indicates it will be much more useable and accessible to APVMA stakeholders.

Electronic gazette

In March 2009, the APVMA sought registrants' views on abandoning the monthly *Commonwealth of Australia Gazette APVMA* (the APVMA Gazette) for an electronic-only version that would be published fortnightly on the APVMA website. There was overwhelming support for the initiative because the more frequent publication will provide registrants with information on regulatory decisions on a more timely basis. It could even, in some cases, help reduce registration timeframes.

This proposal is now being implemented. Concurrent initiatives will include a self-registration facility to enable people to receive email reminders when a new APVMA Gazette has been published, and a customised search tool enabling stakeholders to search keywords across APVMA Gazette issues.

Publication of a list of registration consultants

Registrants are required to submit technical information to the APVMA in seeking registration of their products. This process can be quite difficult for some registrants, so some seek professional assistance. There has however, been no publicly accessible list of consultants that registrants could access. The APVMA consulted with registrant groups and consultants during 2008–09 and developed a list that is now accessible on the APVMA website.

Enhanced media activity

Communicating through the media is an important way of engaging APVMA stakeholders. The APVMA has taken a more proactive stance in recent months in response to heightened public interest in chemical regulation. Information is provided to the media on a more active basis; media statements target regional and national issues; and APVMA spokespeople often appear in the media to explain regulatory processes. A media strategy was developed to capture and formalise these new arrangements.

During the last half of 2008–09, the APVMA received a record number of media enquiries. Issues of interest included the registration status of endosulfan and atrazine, spray drift, comparisons between different regulatory systems, and concerns about possible chemical issues at a Noosa fish farm.

Media training was provided to APVMA staff to increase awareness of how the media works and to alert them to how they can support the media strategy.

Table 14: APVMA presentations

DATE	EVENT	TITLE
July 2008	APVMA Registration Liaison Committee, Canberra ACT	Spray drift
July 2008	APVMA Stakeholder Workshop, Canberra ACT	Cost recovery
July 2008	Department of Primary Industries SmartTrain, Tocal Agricultural College	Minor Use
July 2008	Honey Bee Council Annual General Meeting and Conference	Registration and neo-nicotinoids
July 2008	South Australia Research and Development Institute (SARDI) Conference, Adelaide SA	Pesticide regulations for tree tops
August 2008	National Measurement Institute (Chemical Reference Materials), Sydney NSW	Discussion of current MOU National Measurement Institute, National Registration Scheme and APVMA
August 2008	Forestry industry meetings in South Australia, Victoria and Tasmania	Cat 25 Protocol Assessment for Forestry Industry
September 2008	Korean Food Safety Mission (arranged through DAFF)	Pesticide and veterinary medicine regulation in Australia
September 2008	CropLife Australia Board, Sydney NSW	Efficacy reforms, compliance and impact of changed governance arrangements
September 2008	South Australian ChemCert Conference, Adelaide SA	APVMA's risk management for spray drift
September 2008	National Chemical Trainers Development Group	APVMA's risk management for spray drift
September 2008	University of Sydney, Sydney NSW	Chemical risk assessment
September 2008	Royal Australian Chemical Institute seminar: Audit practices and requirements	Audits of veterinary manufacturing plants and test laboratories
September 2008	14th OIE Seminar on Harmonization of Registration & Control for Veterinary Medicines, Asuncion, Paraguay.	Regulation of veterinary chemical products in Australia
October 2008	University of Sydney, Sydney NSW	Chemical food hazards
October 2008	National Farmers Federation Stakeholders Meeting, Canberra ACT	Spray drift
October 2008	70th Meeting of JECFA, Geneva, Switzerland	Residues evaluations for triclabendazole and tylosin
October 2008	Dairy Industry Advisory Group, Melbourne VIC	On-farm cleansers and sanitisers: non regulatory assessment and approval

DATE	EVENT	TITLE
October 2008	NSW Farmers' Association Meeting, Sydney NSW	Maximum residue limits on crops
November 2008	Veterinary Manufacturers and Distributors Association Annual General Meeting in Sydney NSW	Current regulatory issues and update on the APVMA's veterinary compliance assessment schemes for good manufacturing practice, including costs and fees
December 2008	Meeting Australian Veterinary Association registrants regarding permethrin on 2 December and vaccine registrants and manufacturers, Sydney NSW	Permethrin toxicity in cats Vaccine guidelines
December 2008	OECD Workshop on Lessons Learned with the Planning and Implementation of Joint Reviews of Pesticides Dossiers, Bonn, Germany	OECD InterSAC Process
February 2009	Japanese Delegations, Canberra ACT	Pesticide and veterinary medicine regulation in Australia
February 2009	South Australian Groundsprayers Association, Adelaide SA	Proposed new regulations to mitigate spray drift
February 2009	OECD Risk Reduction Steering Group Meeting, San Francisco, United States of America	APVMA's risk management for spray drift
February 2009	OECD Registration Steering Group Meeting, San Francisco, United States of America	Minor Uses, Expert Group on Minor Uses Progress Report
February 2009	Veterinary product manufacturer industry seminars in Sydney NSW	Regulatory and technical aspects
February 2009	Veterinary product manufacturer industry seminars in Melbourne VIC	Regulatory and technical aspects
February 2009	Veterinary product manufacturer industry seminars, Brisbane QLD	Regulatory and technical aspects
February 2009	Veterinary product manufacturer industry seminars, Perth WA	Regulatory and technical aspects
March 2009	California Department of Pesticide Regulation, California Environment Protection Agency, United States of America	APVMA's risk management for spray drift
March 2009	NSW Groundsprayers Association Conference, Dubbo NSW	Proposed new regulations to mitigate spray drift
March 2009	Charles Sturt University, Wagga Wagga NSW	Residues of ectoparasiticides in sheep tissues

DATE	EVENT	TITLE
March 2009	Horticulture Australia Limited Meeting, Sydney NSW	Residue and Minor Use issues with protected cropping
March 2009	Charles Sturt University Wagga and Orange (by video conference)	Registration of pesticides
March 2009	NSW Sheep Ectoparasiticides Advisory Committee Meeting, Orange NSW	Relevant sheep ectoparasiticide reviews
April 2009	Institute for the Control of Agrochemicals, Ministry of Agriculture(China) Workshop on Risk Analysis of Pesticide Residues, Beijing, China	Risk assessment of pesticide residues and establishment of MRLs in Australia
April 2009	Monash University, Melbourne VIC	Veterinary dosage forms and delivery systems
May 2009	Land & Water Australia's Great Barrier Reef Conference, Cairns QLD	Regulating environmental impacts of pesticides
May 2009	VMDA Members Meeting, Ryde NSW	Draft guidelines and requirements for veterinary herbal remedies
May 2009	Australian Veterinary Association Annual Conference, Darwin NT	Proposed guideline on herbal remedies
May 2009	TGA Nanotechnology Training Forum, Canberra ACT	Potential applications of agvet nanomaterials; Regulatory preparedness strategy at APVMA
June 2009	Plastics and Chemicals Industries Association Conference, Melbourne VIC	The regulatory environment – from challenges to opportunities
June 2009	Aerial Agricultural Association of Australia Convention, Surfers Paradise QLD	APVMA's aerial applications policies
June 2009	OECD Expert Group on Minor Use meeting, Paris, France	Australia Chair
June 2009	OECD Working Group on Pesticides meeting, Paris, France	Minor uses, Expert Group on Minor Uses progress report
June 2009	OECD Working Group on Pesticides meeting, Paris, France	OECD dermal absorption guidance

Strategy 3: Review registered chemicals on the basis of their risk

At 30 June 2009, the Chemical Review team had 29 chemicals listed in the 'Chemicals under review' table <http://www.apvma.gov.au/chemrev/Reviews.shtml#currentreviews>, which is slightly fewer than the 32 listed in 2007–08. Some of these are comprehensive reviews, covering all aspects of the active constituent, product and labels (see Table 15). The remaining reviews focus on more specific aspects of products or their labels.

Table 15: Chemicals under review in 2008–09

2,4-D (c)	Diuron	Molinate
Azinphos-methyl (c)	Fenamiphos (c)	Neomycin
Carbaryl – part 2	Fenitrothion	Omethoate
Carbendazim	Fenthion (c)	Paraquat (c)
Chlorfenvinphos (c)	Fipronil	Parathion methyl (c)
Chlorpyrifos (c)	Macrolide antibiotics	Polihexanide
Diazinon (c)	Maldison (malathion)	Procymidone
Dichlorvos	Methamidophos	Sheep ectoparasiticides
Dimethoate	Methidathion	Thiophanate-methyl
Diquat (c)	Methiocarb (c)	

(c) = covering all aspects of the active constituent, product and labels

In addition to progressing work on a number of the reviews listed above (2, 4-D, carbendazim/thiophanate-methyl, chlorpyrifos, diazinon, dichlorvos, dimethoate, diuron, fipronil, paraquat, and procymidone), review staff spent significant time on the following:

- managing a number of matters arising from the use of existing chemicals which needed prompt regulatory action (see 'Other chemical review activity', page 47)
- conducting preliminary assessments of a number of additional chemicals nominated for possible review by either the Department of Health and Ageing or DEWHA (see 'Pre-review assessments', page 48)
- commencing a series of targetted spray-drift reviews in order to strengthen labels on chemicals that are applied by aerial spraying or ground spraying (see 'Targetted spray drift reviews', page 49)
- maintaining a watching brief and responding to new information about chemicals where the review had been finalised and regulatory action had been previously taken.

Chemical reviews

During 2008–09, the APVMA finalised the remaining component of the atrazine review (raised-bed cropping use pattern), finalised the assessments and outcomes for the fenthion (non-food uses) review, and concluded the review of temephos. Propetamphos was removed from the 'Chemicals under review' list because there are no longer any registered dipping and jetting products for lice treatment on sheep: these products were the specific target of the proposed review.

In additional to finalising a number of formal reviews, the APVMA dealt with other issues relating to existing chemicals (atropine labels statements, creosote, sulphur dioxide generating pads and bromoxynil). Following consultation with stakeholders, registrants agreed to voluntarily vary the registration conditions or to cancel registrations.

The APVMA is pleased with its achievements in the chemical review area, having achieved a balance of mandatory and voluntary variations to registration conditions or voluntary cancellations in line with the target to complete five review decisions during the year.

Chemical review outcomes

Atrazine

The atrazine review was completed in 2007–08 and the final *Atrazine Review Findings and Regulatory Decision* report was published on 1 May 2008. APVMA required amendments to label instructions to further reduce the risk of atrazine entering waterways, to update information about withholding periods, and to provide additional information on how to report herbicide resistance. Registrants who committed to generate additional runoff data were allowed to continue to specify a claim for weed control on triazine-tolerant canola grown on raised beds. However, it became apparent to the APVMA in 2009 that the data were not going to be generated, and so labels that continued to list this use were amended to remove this claim to reduce the risk of atrazine entering waterways. This completes the final component of the atrazine review. The APVMA continues to assess new information made available.

Fenthion (Part 1: Uses of fenthion in non-food-producing situations)

The preliminary assessment conducted in 2005 identified that product labels did not contain adequate instructions to allow safe use, or use could lead to unintended impacts on non-target birds and risk to the environment. Following extensive consultation with the states and territories to mitigate these risks, bird control products containing fenthion are in the process of being declared 'Restricted Chemical Products'. (This declaration will also include bird-control products containing alphachloralose and 4-aminopyridine vertebrate control products.) This part of the fenthion review will be finalised when DAFF includes these products in the List of Restricted Chemical Products in Schedule 4 of the Agvet Code Regulations.

Temephos

The registrant of the single temephos sheep-dipping and jetting product on the Australian market pre-empted the finalisation of the temephos review by submitting amendments to the product label. The APVMA decided to conclude the review because the registrant voluntarily amended the label. The component assessment reports which were prepared for the review of temephos have been posted on the Chemical Review section of the APVMA's website.

Virginiamycin

An outcome was reached in the review of virginiamycin. A registrant sought review in the Administrative Appeals Tribunal of APVMA's decision to impose certain re-treatment intervals on the product labels. The APVMA and the registrant reached agreement on a modified regulatory outcome and the proceedings before the Tribunal were settled. The regulatory outcome was that the approved labels require veterinarians to prescribe virginiamycin in a way that is consistent with the Australian Veterinary Association Code of Practice for Prescription and Use of Products which contain Antimicrobial Agents. The code of practice was developed in conjunction with the Australian Veterinary Association and includes a specific instruction in relation to virginiamycin. The restraints on the product label have been designed to preclude veterinarians prescribing the use of virginiamycin in any other situation.

The review of virginiamycin had always accepted that there was a need for virginiamycin clinical situations, namely to treat necrotic enteritis in broiler chickens and lactic acidosis in cattle. Both the label and The Code of Practice for Prescription and Use of Products which contain Antimicrobial Agents requires veterinarians to investigate non-antibiotic options before prescribing the use of virginiamycin. Each also requires veterinarians to review farm records on the use of virginiamycin to ensure compliance with prescribing instructions.

The regulatory outcome reached in the Administrative Appeals Tribunal ensures cautious use of virginiamycin only in situations where it is clinically required and in a way that minimises the emergence of antimicrobial resistance.

Other chemical review activity

Other issues relating to existing chemicals dealt with during the year are below.

Atropine

The APVMA asked the Department of Health and Ageing to consider the most appropriate treatment for organophosphorus and carbamate poisoning in Australia and make a recommendation about the current labels for these chemicals. Labels required users to have a supply of atropine tablets, an antidote therapy, available when using these insecticides. A problem arose because oral forms of atropine are no longer available and injectable forms are available by prescription only. Furthermore, there were concerns that any therapeutic intervention in poisoning cases should be done under the guidance of a health professional. The APVMA has asked affected registrants to amend the first aid and safety directions on their labels—this will remove references to obtaining a supply of atropine tablets. These amendments are to be completed within two years from the date of gazettal of the notice (April 2009).

Creosote

As a result of the rescheduling of creosotes by the National Drugs and Poisons Scheduling Committee, creosote products used for the treatment of timber can no longer be supplied for use around the home. Products are restricted for use in agricultural, industrial and commercial situations. The APVMA reassessed the labelling of all creosote products that were registered in 2004. As a result, many of the products were voluntarily withdrawn: only one registered creosote product remains. This registrant agreed to voluntarily restrict its use, addressing human health and environmental concerns. Creosote has now been removed from the chemical review nomination list.

Sulfur dioxide generating pads and sheets for post-harvest storage of grapes

While a formal review of sulphur dioxide generating pads was not required, registrants were required to amend their labels. These changes provide clearer instructions for the storage and re-handling of grapes packed with these products as well as warnings for sulphite-sensitive and asthmatic workers, updated safety directions, and disposal instructions for the product after use.

Bromoxynil

Bromoxynil is the active constituent in a number of herbicide products commonly used to control a wide range of weeds in food crops, pastures and fodder. Recently, new information relating to bromoxynil residues in treated food crops, pastures and fodder crops showed that residues in these crops decline at a much slower rate and are more readily transferred to animals than previously thought. In light of this new information, the APVMA completed an assessment of bromoxynil and all products containing bromoxynil. The results indicate the withholding periods (currently 14 days for grazing and for cutting for stockfood) need to be increased to eight weeks. Additionally, the label amendments will also encompass spray drift risk mitigation measures. The APVMA has advised registrants of forthcoming regulatory actions to increase the grazing withholding period to eight weeks and include protective no-spray zones. This regulatory action will be completed in 2009–10.

Carbendazim and thiophanate-methyl

Labels for these products have been suspended since May 2007. The suspension was extended for a further twelve months from June 2009 while the review of carbendazim and thiophanate-methyl is conducted. Carbendazim products must carry additional warnings and safety directions relating to developmental concerns. These warnings were not necessary for thiophanate-methyl.

Triasulfuron

APVMA Residues chemists identified statements on triasulfuron product labels that could have been misinterpreted, potentially allowing use of the chemical up until harvest and thus leading to exceedances of MRLs in harvested crops. Registrants were asked to amend their labels accordingly.

Updating labels of grandfathered products

A project to update labels of grandfathered products was started in 2000 to cover all those products that were registered under the transitional arrangements between the Australian Government and the states and territories that existed at the time of the creation of the APVMA (then the National Registration Authority) in March 1995. At the request of the APVMA, most registrants updated their product labels and confirmed their registration details. Of the remaining products, several more were dealt with in 2008–09. This leaves only a small number remaining to be actioned, of which many are only shelf products (they are not currently marketed).

Pre-review assessments

During the year, the APVMA conducted initial scoping and preliminary considerations of 22 compounds. All but one of these are listed on the priority candidate review list, which is published at <http://www.apvma.gov.au/chemrev/nominations.shtml>. This work is carried out before deciding whether a comprehensive or targetted review is required and to determine which data will be required to address specific issues of concern.

Management of off-target damage from spray drift

Liaison with stakeholders on regulatory proposals for the management of spray drift

The APVMA organised several stakeholder meetings during the year to consider possible risk management measures to reduce the risk of off-target damage from spray drift. In July 2008, the APVMA met with state and territory control-of-use coordinators and representatives from a range of user groups; this meeting was joint initiative of the APVMA and the National Farmers' Federation.

Because there have been many incidents of reported phenoxy herbicide damage to cotton crops, the APVMA also met with Cotton Australia on several occasions. The CEO of APVMA—together with the Chair of the Advisory Board, the manager of the APVMA's Chemical Review and Adverse Experience Reporting Program, and APVMA's Principal Scientist (Agricultural Chemicals)—visited Narrabri in January to meet with cotton growers and see the problem first hand. This was followed by a further meeting at the APVMA in Canberra to discuss practical options for limiting off-target damage from the use of herbicides.

Targetted spray drift reviews

In July 2008, the APVMA advised that it would require label amendments on products that are applied by spraying. The amendments are aimed at mitigating risks arising from spray drift (see *APVMA Operating Principles in Relation to Spray Drift Risk,* which is available at the APVMA website). The APVMA has completed spray drift risk assessments for all 2,4-D products (164 products) and all other phenoxy herbicide products (>150) containing the active constituents 2,4-DB, dichlorprop, MCPA, MCPB and mecoprop. Product labels will be required to state that there should be no-spray zones in downwind areas to protect aquatic life, non-target native vegetation and crops.

The APVMA will require affected registrants to amend phenoxy herbicide product labels to mitigate risks identified in these assessments.

Other projects

Pest management in schools

In August 2008, the APVMA developed a website publication that provides information on pest control in schools and guidance on the safe and effective use of pesticides in and around school premises. The APVMA made several amendments to improve the document's usefulness and published another version in August 2009.

Expanding and updating the APVMA's review website

In 2008–09, the Chemical Review team continued to rationalise and expand the Review section of APVMA's website to include more detailed information about chemicals that have been reviewed or have otherwise been the subject of significant regulatory action in Australia. For example, a document outlining the regulatory history of the so-called 'organochlorine' pesticides and their ultimate removal from the market has been added to the website. This work is designed to make the website more informative for a range of stakeholders.

International engagement

The Australian Government, through the APVMA, is engaged in multiple international forums. Through this international engagement and association, the APVMA contributes to international best practice regulations of chemicals with our technical and operational policy expertise.

Organisation of Economic Co-operation and Development (OECD)

The APVMA has attended and participated in the OECD Working Group on Pesticides (represented by the CEO and the Pesticides Program and Minor Use managers), the Registration Steering Group and Risk Reduction Steering Group (represented by the Principal Scientist, Pesticides and the International Co-ordinator), and the Biopesticides Steering Group represented by the manager of the Minor Use team.

APVMA staff also attended several expert working group meetings and workshops for Minor Use, residue chemistry, spray drift, electronic submissions and transport mechanisms, and international joint reviews.

Joint reviews and work-share activities

This financial year the APVMA progressed one joint pesticide review to its final stages, and began another three joint reviews of new active constituents and their formulated products. Of the three joint review activities commenced, two are trilateral reviews undertaken with the United States Environmental Protection Agency and the Pest Management Regulatory Agency in Canada, while the third project involves the United States, Canada, the European Union (with Germany as rapporteur) and New Zealand. One application has also been received that has already been assessed in the European Union (with United Kingdom as rapporteur). The hazard assessment undertaken by the European Union will be used in the Australian evaluation under work-sharing arrangements. The role of the APVMA and its advisory agencies in these joint reviews is in the capacity of primary reviewer for some assessments and secondary reviewer for other assessments. The APVMA has also been involved in the planning stages for another eight proposed joint reviews, seven of which are expected to begin in 2009–10. The APVMA has continued to participate in the OECD Ad Hoc Exchange Program of review reports, by sharing and receiving assessment reports with chemical regulators from other OECD member countries.

International engagement and Minor Use

The APVMA maintained its active involvement in international activities associated with Minor Uses. This included representation as Chair of the OECD Expert Group on Minor Uses. The activities of this group included:

- conducting a survey on approaches and requirements for efficacy and crop safety
- investigating regulatory incentives for registration and approaches to liability for Minor Uses
- developing OECD guidance documents on defining Minor Uses and solving Minor Use gaps.

During 2008, a Codex Committee for Pesticide Residues Electronic Working Group on Minor Uses developed a discussion paper on ‘Guidance to facilitate the establishment of Codex MRLs for Minor Uses and specialty crops’. The APVMA participated in this working group as co-chair with the United States (Chair) and Kenya (co-chair). The Codex Committee has recommended that the working group continue and target the identification of areas for potential Codex MRL priority for minor and specialty crops.

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH)

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is a trilateral (European Union – Japan – United States) program aimed at harmonising technical requirements for registration of veterinary products. Australia and New Zealand have observer status at VICH meetings, and a New Zealand Food Safety Authority officer currently represents Australia and New Zealand.

An APVMA officer attended a VICH Pharmocovigilance Expert Group meeting in Japan in January 2009. The Principal Scientist, Veterinary Medicines represents Australia and New Zealand on a VICH expert working group that is developing new guidelines on assessment of drug residues in animal-derived foods.

An APVMA officer also represented the APVMA at the 14th World Organisation for Animal Health Seminar on Harmonization of Registration & Control for Veterinary Medicines.

Joint Meeting on Pesticide Residues in Food (JMPR) & Joint Expert Committee on Food Additives and Contaminants (JECFA)

The JMPR and JECFA are international scientific expert groups that are jointly administered by the Food and Agriculture Organization and the World Health Organization (WHO). In September 2008, the Manager, Chemical Review and AERP attended as an invited expert member of the WHO Toxicology Panel of the JMPR. In October 2008 the Principal Scientist, Veterinary Medicines attended as an invited expert member of the Expert Committee on Food Additives and Contaminants.

The JMPR provides recommendations on maximum residue levels to the Codex Committee for Pesticide Residues for the establishment of Codex MRLs for trade. This committee met in April 2009. The Program Manager, Pesticides attended as part of the Australian delegation and alternate delegation leader.

Codex Committee on Residues of Veterinary Drugs in Food

The JECFA provides recommendations on maximum residue levels of veterinary drugs to the Codex Committee on Residues of Veterinary Drugs in Food. This committee met in May, and the APVMA's Manager, Veterinary Residues attended as part of the Australian delegation and as the Chair of the Working Group on Priorities, which establishes the list of veterinary medicines for which MRLs will be determined.

Other international activities

The APVMA has continued its international engagement through hosting international visits and targeting staff visits to other regulatory agencies. During the financial year, APVMA staff met with representatives of the Japanese government, the United States Environment Protection Agency, the United Kingdom Chemical Regulatory Directorate and Veterinary Medicines Directorate, the European Medicines Agency and the New Zealand Food Standards Authority.

OUTPUT 1.2: RESPONSIVE FEEDBACK MECHANISMS AND QUALITY ASSURANCE AND COMPLIANCE PROGRAMS THAT SUPPORT ONGOING CHEMICAL PRODUCT QUALITY AND CONFORMANCE WITH LEGISLATION

The APVMA monitors the quality and safety of registered pesticides and veterinary medicines through four programs: Chemical Review, Compliance, the Adverse Experience Reporting Programs (AERP), and the Manufacturers' Licensing Scheme.

It is through these programs that the APVMA can take regulatory action if the registration standards are not maintained or if new information suggests that a product's registration should be reconsidered. Within these programs, three key strategies are used to ensure the ongoing quality of pesticides and veterinary medicines:

Strategy 4: Consider stakeholder feedback including adverse experience reporting

Strategy 5: Ensure industry compliance with the legislation, including maintenance of quality assurance programs

Strategy 6: Respond to and manage emerging regulatory issues

Strategy 4: Consider stakeholder feedback including adverse experience reporting

The main mechanism for considering stakeholder feedback on adverse experience reports is through the AERP for pesticides (AERP *Ag*) and veterinary medicines (AERP *Vet*). These two programs are post-registration feedback loops that the APVMA has established to facilitate responsible management of pesticides and veterinary medicines throughout their life.

The aims of AERP *Ag* and AERP *Vet* are to provide the APVMA with feedback about the quality and performance of pesticides and veterinary medicines in the field. This information helps to ensure that the APVMA's registration decisions are appropriate and that they promote and maintain public confidence in the National Registration Scheme. Consideration of adverse experience reports frequently involves consultation within the APVMA as well as with other relevant Australian, state and territory government departments, monitoring agencies in other countries, recognised experts on advisory committees and product registrants.

The AERP considers reports relating to:

- animal health issues, including both domestic and native birds and animals
- damage to crops and plants
- human health issues, where people are exposed to veterinary medicines or pesticides
- lack of efficacy
- residue issues
- environmental damage.

Links have been established with the Poisons Information Centre in Sydney and Brisbane as alternative sources of feedback about the safety of pesticides and veterinary medicines.

AERP Ag

The APVMA raised community awareness of AERP *Ag* in 2008–09 by:

- publishing the *Report of Adverse Experiences for Veterinary Medicines and Agricultural Chemicals 2007*
- encouraging reporting through the networks of members of the Community Consultative Committee
- a Community Consultative Committee member presenting a paper to the ChemCert Conference at Bendigo, Victoria in May 2009 promoting the AERP
- presenting a session at the ChemCert Course held in Bairnsdale in May 2008
- promoting the AERP at the East Gippsland Field Days May 2008
- establishing contact with appropriate business and individuals in the East Gippsland region including Sale, Bairnsdale, Orbost and Traralgon in May 2008
- presenting a series of six articles and advertisements in the Bendigo regional paper in April and May 2008
- preparing a standard short reporting form
- initiating a review of the AERP *Ag* Registrants Component
- including an AERP article and banner advertising in *Farm Guide* magazine 2009.

During 2008–09, the APVMA assessed and classified 179 adverse experience reports related to pesticides. The APVMA also responded to enquiries received from the public. Adverse experience reports involving effects on crops or target areas accounted for approximately 40 per cent of the reports, lack of effect accounted for 2 per cent of reports, environmental or non-target effects for 29 per cent of reports, and human adverse experience reports for 29 per cent.

Several off-target spray events have been considered with assistance from state authorities. Specific chemicals could not be targetted in most cases. The environmental and off-target reports are being considered by the Chemical Review team as part of a project to consider regulatory controls of phenoxy-type herbicides.

Around 400 responses received following a call from registrants for reports of adverse experiences they were aware of. Many indicated that they had not received adverse reports.

AERP Vet

Activities undertaken in 2008–09 to raise awareness of AERP *Vet* and to advise the community of the potential risks associated with the use of veterinary medicines included:

- publishing the *Report of Adverse Experiences for Veterinary Medicines and Agricultural Chemicals 2007*
- an AERP article and banner in advertising in the *Farm Guide* magazine 2008
- proactively managing issues associated with permethrin toxicity in cats
- participating in the Pharmicovigilance expert working group as part of the APVMA commitment to the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products.

During 2008–09, AERP *Vet* assessed and classified 1688 reports, involving suspected adverse reactions in animals, received from veterinary surgeons, owners, members of the public and product registrants. Numerous enquiries were received from veterinarians and members of the public. Of the adverse experience reports, 77 per cent involved animal safety, 19 per cent involved lack of efficacy and 3 per cent involved human health issues.

Strategy 5: Ensure industry compliance with the legislation, including maintenance of quality assurance programs

A core regulatory activity of the APVMA is to ensure that active constituents, chemical products and promotional material comply with regulatory standards set during evaluation and registration. The APVMA Compliance section undertakes a variety of monitoring and surveillance activities to facilitate and ensure industry complies with these requirements. Compliance is enforced when necessary through a suite of methods that include warnings, recall and prosecution.

Quality Assurance Scheme for Agricultural Actives and Products (Ag QA Scheme)

The Ag QA scheme provides an assurance that to the community that pesticide registrants use approved and compliant active constituents in the formulation of pesticide products.

Conditions of product registration are imposed requiring registrants to supply only products containing active constituents that conform to APVMA standards, and to keep batch production and supply records relating to active constituent quality. Product testing is undertaken to crosscheck the accuracy of record keeping.

During the latter half of 2007–08 and throughout 2008–09, the Compliance team has been involved in complex enforcement activities, which resulted in fewer resources being available for operation of the Ag QA Scheme. Unfinished audits scheduled for the 2007–08 year were completed in 2008–09.

Record inspection by monitoring visits and data call-ins

The Compliance team conducted eight company-monitoring visits that resulted in the inspection of 56 batch records of 22 products (Table 16). No desk-based reviews were conducted. At company visits, monitoring is interactive in that companies have the opportunity to present records during the audit. Records were reviewed comprehensively by the APVMA to ensure the records comply with the published APVMA standard and with any relevant requirements from the conditions of registration. No data call-ins were conducted during the year.

Table 16: Results of batch inspections under the Ag QA Scheme in 2008–09

TYPE OF CHECK CONDUCTED (NO. OF PRODUCTS)	NO. OF BATCHES	MET THE APVMA STANDARD	ADEQUATE RECORDS	CONTINUITY
Monitoring visit (22)	56	56	56	54

Compliance with the conditions of registrations was categorised according to:

1. whether the batch fully complied with the conditions (it met the APVMA standard, had adequate records, and records showed continuity)
2. whether the recorded particulars showed that the batch met the APVMA standard
3. whether records of the batch were adequate to demonstrate compliance
4. whether the records showed continuity—that the active constituent batch analysis records could be linked to a particular batch of product supplied into the Australian market.

Record inspections did not uncover any non-compliance. All of the 56 batches inspected fully complied with the conditions of registration. In keeping with the focus on maintaining active constituent quality and not pursuing minor record keeping errors (4 per cent), the APVMA issued formal warnings to registrants who failed to submit adequate records or failed to establish continuity between records. Such warnings can include increased record inspections during subsequent inspection cycles.

Product testing

During 2008–09, the Compliance team continued to sample and test products ready for supply into the marketplace and check on the accuracy of batch records submitted under the Ag QA Scheme.

Compliance staff were also involved in a greater level of sampling and testing as a result of increased enforcement activities during the year. This testing involved four products containing active constituents from an unknown source, twelve samples of products containing generic omethoate, six samples of products containing benzalkonium chloride to determine efficacy, and a sample of a neem product to determine azadarachtin content. As a result of this work, the testing program for 2008–09 was delayed.

Glyphosate products

Eighty-four glyphosate products were sampled in 2008–09; testing will be completed in early 2009–10.

Triadimefon, triadimenol, pyrimethanil, metolachlor, diazinon, propineb and chlorthal-dimethyl products

Products containing the active constituents triadimefon (13 products), triadimenol (16 products), pyrimethanil (five products), metolachlor (seven products), diazinon (five products), propineb (two products), and chlorthal-dimethyl (one product) were sampled, and the analytical results for levels of toxicologically significant impurities relative to active content were compared with the records provided by registrants. This sampling started in 2007–08 and finished in 2008–09.

Initial testing for triadimenal and triadimefon products found that four products had an active constituent concentration below the allowable tolerance. After further investigation, the registrants satisfied the APVMA that the active constituents levels were compliant. All of the products were compliant with the standard for impurity concentration.

One of the diazinon products did not result in a compliant assay. However, the method of analysis used did not appear to appropriate for this particular formulation. The registrant was subsequently able to establish that the particular batch was compliant.

Analytical difficulties have been encountered during testing of propineb samples and the testing laboratory is working with the APVMA to resolve the issues.

All metolachlor, chlorthal-dimethyl and pyrimethanil products were compliant.

All test results show a high level of compliance with APVMA standards for the quality of the active constituent incorporated into products and the level of active constituent within those products.

The records presented by the registrants, kept as part of the conditions of registration, generally support the analytical results found during testing by the APVMA. Where the APVMA finds a significant difference between the records and the testing results, the registrant (and its activities) may be subject to increased levels of monitoring by the Compliance team.

Reports of non-compliance

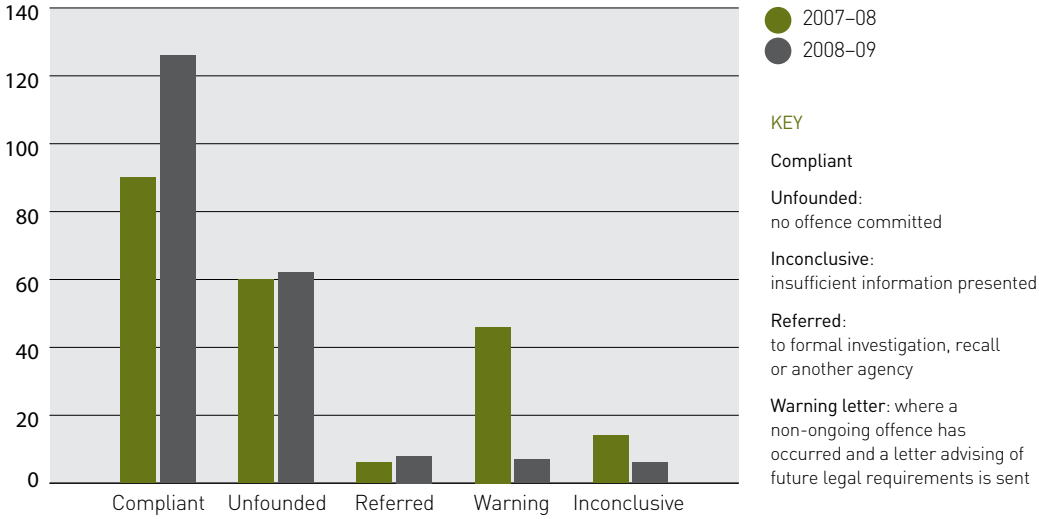
The APVMA encourages industry and the public to report the advertising and supply of unregistered and unapproved chemicals or promotion of products inconsistent with approved labels.

During 2008–09, 203 new reports were received, all of which were acknowledged and assessed for action based on the risk posed by the chemicals involved. Fifty-three per cent of all non-compliance reports were completed within three months of receipt.

Of the 209 reports finalised this year, 133 reports were finalised through warnings and negotiated compliance (Figure 5). Reports assessed as representing a low to medium, or continuing risk, are typically managed this way.

Reports assessed as representing a potential or actual high risk are dealt with by an inquiry: this can escalate to an investigation, which could lead to prosecution or a product recall. In the 2008–09 financial year, no reports were escalated to a product recall, several reports resulted in a visit to the company to monitor compliance, and three reports were referred to investigation.

Figure 5: Outcome of inquiry into reports of non-compliance



Auditing of permit conditions

During 2008–09, two APVMA permit conditions audits were conducted, both of which discovered discrepancies regarding the permit holders' adherence to the permit conditions. Closure of these permit audits will be carried forward into the new financial year. Formal APVMA permit auditing is a new operational area for the Compliance team.

Investigations and recalls

During 2008–09, the APVMA initiated six new investigations and continued with two investigations initiated in 2007–08. These investigations relate to the following allegations:

- Unregistered pesticides were allegedly supplied in contravention of section 78 of the Agvet Code. A detailed investigation was conducted and it was found that insufficient evidence could be gathered to establish a *prima facie* case. The investigation was closed during 2008–09.
- Numerous allegations were made under section 136 of the Commonwealth Criminal Code (supply false or misleading information). This investigation continued throughout 2008–09, and it still remains active.
- A range of unregistered veterinary chemical products was found by the APVMA to have been supplied in contravention of section 78 of the Agvet Code and section 121(5) of the Agvet Code (contravene a condition of a licence to manufacture). The brief has been referred to the Commonwealth Director of Public Prosecutions for determination.
- A range of unregistered antifouling paint products was found by the APVMA to have been supplied in contravention of section 78 of the Agvet Code. A detailed brief of evidence is being prepared.
- An allegation was received that unregistered agricultural chemical products were being used in a variety of grape growing regions. The APVMA conducted a joint investigation with Department of Primary Industry in Victoria but found no evidence of the supply. Information and education was provided to growers in this area.
- An allegation was received that a company was supplying two unregistered veterinary chemical products into the market. An investigation was conducted and certain information obtained. It was established that no offences of supplying unregistered products could be established.
- A report was received by the APVMA that a registered product was sold without any labels. Following an investigation with the assistance of the Department of Primary Industry in Victoria, the company involved conducted a complete audit of its product and found issues with labelling procedures. Administrative action was taken by the APVMA to resolve this investigation.
- An allegation was received by the APVMA that an unregistered equine product was being supplied. An investigation is still underway into this matter, but at this point the product has been removed from the market. A complete review of all products supplied by this company is underway in an attempt to bring them into compliance.

During 2008–09, seven recalls that had been initiated during 2007–08 were finalised.

In addition to these recalls, the Compliance team registered a further fourteen new voluntary recalls and six new compulsory recalls during the year.

There were 18 voluntary recalls and nine compulsory recalls during 2008–09. Of these, four voluntary recalls and five compulsory recalls were closed during the period, noting that several recalls were pending only formal closure as at 30 June 2009.

As at 30 June 2009, 14 open voluntary and four open compulsory recalls remain. These recalls will be carried forward into the new financial year.

Hormonal growth promotants

The European Union requires continued assurance from Australia that beef and beef products imported by its member states have not been treated with hormonal growth promotant (HGP) products. To provide this assurance, the Australian Government and state and territory governments have put in place the National Hormonal Growth Promotant Monitoring and Control System. The system enables Australian authorities to account for the importation, supply and use of HGPs. The APVMA plays a significant role in the operation and management of the system by authorising importers and resellers, and requiring that accurate records of supply be kept. At 30 June 2009 there were 286 APVMA-authorised suppliers.

The APVMA continued to operate a compliance audit program of authorised HGP suppliers. The frequency of audit is determined on a risk basis and includes verification or a follow-up audit to confirm that major corrective actions identified during the first visit have been carried out. During the year, the APVMA audited 60–HGP authorised suppliers (both retailers and wholesalers). Seventy-three per cent of the suppliers were found to be compliant on the first visit. Twenty-seven per cent were issued with a warning and subjected to more frequent audits. All suppliers (100 per cent) were compliant when audited for a second time.

Consent to Import

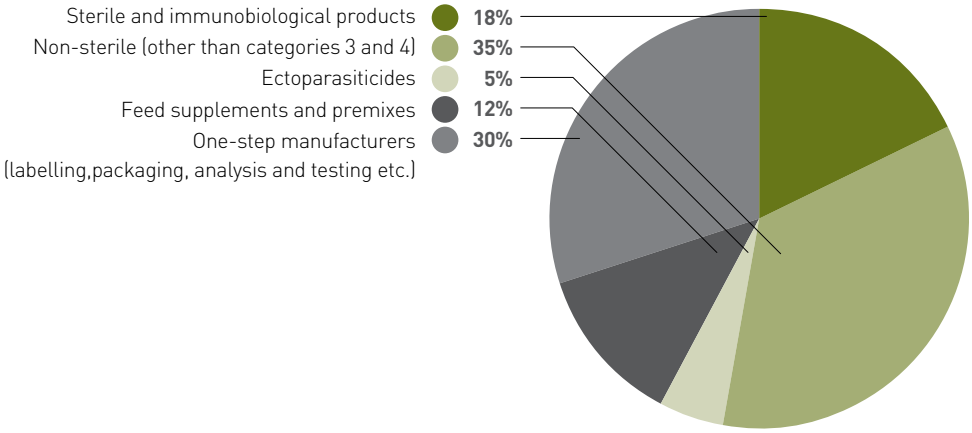
The APVMA monitors the importation of pesticides and veterinary medicines to limit the potential distribution of unregistered and unapproved chemicals in the Australian marketplace. In 2008–09, it conducted enquiries into eight matters involving importation. The APVMA issues Consents to Import for unregistered and unapproved chemicals where a legitimate reason exists for a person or a company to have possession of the chemicals in Australia. The APVMA assessed 383 applications and issued 338 Consents to Import. Of these, 176 were issued to allow importation for use under the APVMA general permit, 60 were issued with permit applications, and 112 were issued to veterinarians. Sixty-one applications for consent were not approved or were found to be unnecessary.

Manufacturers' Licensing Scheme (MLS)—compliance with good manufacturing practice

The APVMA established the Manufacturers' Licensing Scheme (MLS) in 1996, in response to concerns over the quality of veterinary medicines. Industry and government recognised that quality needs to be 'built into' rather than 'tested into' veterinary medicines. The primary objective of the MLS is to assure, and give confidence in, the quality of veterinary medicines manufactured and supplied in Australia. To obtain and maintain a licence under the scheme, manufacturers must demonstrate compliance with the APVMA's manufacturing principles and the associated Australian Code of Good Manufacturing Practice for Veterinary Chemical Products (GMP). APVMA-authorised auditors or auditors from specified authorities periodically audit manufacturing facilities to confirm that they are compliant.

At 30 June 2009, a total of 212 Australian-based manufacturers were licensed or being assessed for a licence (see Figure 6). During the financial year, APVMA-authorised auditors conducted 87 facility audits and APVMA staff conducted two unannounced audits. The APVMA issued 20 new licences and amended 119 existing licences. The APVMA also issued 30 notices of intent to suspend or cancel licences or to impose conditions. During the last financial year, 28 licences were cancelled (17 voluntarily and 11 imposed by the APVMA), and two licences were suspended. Conditions continued to be imposed on all new and existing licences to improve compliance and overcome delays in responding to audit findings.

Figure 6: Percentage of manufacturers licensed or being assessed for a licence, under the Manufacturers' Licensing Scheme, by category, at 30 June 2009



The APVMA arranged an auditors' workshop in May 2009 to analyse recent trends in reported non-conformances, to review the effectiveness of auditing processes, to provide detailed feedback to the auditors, and to determine audit priorities for the coming year. Licensed manufacturers have continued to provide positive post-audit feedback concerning audits and auditors: 95 per cent of manufacturers provided a rating of greater than seven out of ten.

The APVMA continued to provide assistance to manufacturers, primarily through feedback to enquiries and follow-up to audits. The operation of the scheme provides confidence that veterinary medicines are manufactured in Australia according to quality standards.

Industry GMP seminars

The veterinary industry associations organized a series of seminars, entitled 'Seminars on Good Manufacturing Practice (GMP) – regulatory and technical aspects'. The seminars were held in Sydney, Melbourne, Brisbane and Perth in February and were attended by 238 registrants representing approximately 100 veterinary product manufacturers and 16 industry consultants. Mr Ian Wheatley, one of the APVMA's authorised GMP auditors, provided training on technical aspects of GMP; and APVMA GMP staff presented a session on regulatory and operational aspects of audits and licensing. Feedback from the attendees and the industry associations has been very positive, and the content was well received.

Imported veterinary products

The APVMA introduced the Veterinary Post-registration Overseas GMP Compliance Scheme (the Overseas GMP Scheme) in 2005 to provide assurance that overseas manufacturers that supply veterinary medicines to the Australian marketplace comply with GMP requirements.

Applicants for product registration must demonstrate that the imported product is manufactured to quality standards comparable to those applying to Australian-based manufactures of veterinary medicines. During 2008–09, some 203 overseas manufacturing sites were assessed for compliance with Australian manufacturing standards as part of the product application assessment process. APVMA-authorised auditors also conducted 19 audits of overseas manufacturers.

As imported products are registered, conditions of product registration are applied to ensure continuing compliance with the GMP requirements. The APVMA monitors registrant compliance with these conditions of product registration by requesting that selected registrants provide current evidence of GMP compliance (the post-registration process). During 2008–09, GMP records were requested for 217 imported products. Satisfactory evidence was provided for 157 products, and the remaining cases are still being progressed. Although the overall objectives of the scheme are being met, nearly 34 per cent of registrants were not able to provide the necessary evidence within the required timeframe.

Australia has a mutual recognition agreement with the European Union and the European Free Trade Association, under which both signatories have a sectoral annex for medicinal products, GMP inspection and batch certification. These agreements continue to be monitored and maintained.

The APVMA conducted a review of the Overseas GMP Scheme and published the final report in November 2008, after substantial industry consultation. This report reviewed Overseas GMP Scheme that was introduced in October 2005.

The review was conducted to determine whether the Overseas GMP Scheme is effective in assuring that imported veterinary medicines are manufactured in GMP compliant facilities. The review requested feedback about experiences with the Overseas GMP Scheme, whether it had affected GMP compliance generally, and whether it is useful. It also examined whether the Overseas GMP Scheme was meeting its original objectives.

The primary concerns of key stakeholders related to difficulties with obtaining evidence of GMP compliance from overseas authorities and the need for further clarification in the APVMA's *Guidelines for Providing Evidence of GMP Compliance.* The findings from the review outlined a number of proposals to address these concerns, and the APVMA will progress them in the coming year. The review indicated that the Overseas GMP Scheme has had a positive impact on the GMP compliance of overseas manufacturers and that there are few changes required to the scheme's administrative processes.

Export assistance

Many foreign governments require evidence of compliance with GMP to be provided before veterinary medicinal products can be imported. The APVMA endeavours to assist the export of Australian-made veterinary products by providing certificates of manufacture upon request. Such certificates confirming the licensing status of Australian manufacturers are recognised and accepted by many countries including Brazil, Egypt, Indonesia, Malaysia, the Philippines, Saudi Arabia, Singapore, South Korea, Taiwan

and Thailand. Countries in the European Union and the European Free Trade Association also accept certificates issued under the terms of two mutual recognition agreements.

During 2008–09, the APVMA issued 76 export certificates for compliance with Australian manufacturing standards.

Strategy 6: Respond to and manage emerging regulatory issues

The Australian Government and COAG have set a challenging reform agenda, including chemicals and plastics reforms. An APVMA reform team has been working towards developing and implementing these reforms. The reform team is also responsible for the progression of internal reforms as identified by external audits and operational requirements.

Australian National Audit Office (ANAO) audit of the APVMA

The ANAO conducted a performance audit of the APVMA in 2006. The audit was extensive and assessed whether the APVMA was delivering its key regulatory functions effectively.

The ANAO audit report contained six recommendations dealing with:

1. improved management of conflict of interest for advisory committees and service providers
2. improving reporting and transparency of registration timeframe performance
3. strategies for improving the quality of applications
4. the arrangements for receiving scientific advice from government agencies
5. improving the MLS
6. optimising the management of throughput and transparency within the Chemical Review team.

The APVMA welcomed the report and agreed with all six recommendations. The report acknowledged various initiatives that the APVMA had introduced in recent years to improve the effectiveness of its operations. However, the arena of chemicals regulation is constantly changing and the report provided valuable recommendations for further improvements.

In 2008–09, the APVMA has continued activities to complete its implementation of the ANAO recommendations. At 30 June 2009 the APVMA had implemented recommendations 1, 2, 4 and 5. Activities in relation to Recommendation 3 have progressed positively, and the systematic recording and analysis of application errors and omissions will start early in the 2009–10 financial year. Although Recommendation 6 has been partially addressed through the adoption of new communications approaches, the further progression of that reform has been delayed pending the overall review of the National Registration Scheme under the COAG chemicals and plastics agenda (see below).

Further detail on the ANAO audit, the ANAO's recommendations and the APVMA's implementation activities is available on the APVMA's website at <http://www.apvma.gov.au/about_us/anao_report.shtml>.

COAG Chemicals and plastics regulation reform agenda

As an outcome of the work of the Regulation Taskforce and the publication of '*Rethinking Regulation: Report of the Taskforce on Reducing Regulatory Burdens on Business*' (the Banks Report) in January 2006, the Australian Government commissioned the Productivity Commission to conduct a study of chemicals and plastics regulation. It was intended that the recommendations of the study would inform the COAG Ministerial taskforce on chemicals and plastics regulation reform in developing measures to streamline national chemicals and plastics regulation.

Before the release of the Productivity Commission's final research report on chemicals and plastics regulation in August 2008, the Ministerial Taskforce sought to consolidate a range of reforms that could be progressed in the short term. At its July 2008 meeting COAG agreed to a number of 'early harvest' reforms of relevance to the regulation of agricultural and veterinary chemicals, including:

- **Reform 3:** Recognition by Food Standards Australia New Zealand of the APVMA's residue risk assessment and the promulgation of the resulting maximum residue limits to the Food Standards Code
- **Reform 4:** The Australian Government should progress industry reforms for regulating on-farm dairy cleansers and report progress to COAG
- **Reform 5:** The Australian Government should progress industry reforms for regulating water sanitisers for industrial use
- **Reform 7:** Exclude certain agricultural and veterinary products that are currently regulated by the APVMA from the National Registration Scheme on the basis of risk
- **Reform 8:** Agricultural and veterinary chemical labelling reform – regulatory box
- **Reform 9:** Improve data protection provisions for agricultural product registrants
- **Reform 10:** Regulatory process for low risk agricultural and veterinary chemicals
- **Reform 12:** Various amendments to agricultural and veterinary chemical legislation

Two other reforms were agreed by COAG but are now to be addressed through overall review of the National Registration Scheme (see below). They are:

- **Reform 6:** Access to high-risk agricultural and veterinary chemicals is restricted to those with the necessary competencies in order to ensure that they are not misused and, as a result, withdrawn from the market
- **Reform 13:** National scheme for regulating the aerial application of agricultural chemicals

In 2008–09, the APVMA has been active in developing and delivering operational reforms and contributing to policy reform activities. The APVMA has primary carriage of 'early harvest' reforms 8 and 10 and has worked to progress these. It has also had significant involvement in the progression of reforms 4, 5 and 7, for which DAFF has primary carriage. The APVMA has also continued to assist and inform the other policy reforms.

The Productivity Commission's final research report on chemicals and plastics regulation contained two recommendations relevant to pesticides and veterinary medicines. These related to the efficiency and cost effectiveness of chemical assessments (Recommendation 8.1) and a single national framework for control of use (Recommendation 8.2). At its November 2008 meeting, COAG endorsed the recommendations and directed the Primary Industries Ministerial Council (PIMC) to develop proposals for COAG consideration in 2010. In response the Product Safety and Integrity Committee, a sub-committee of PIMC, has commissioned a review of the National Registration Scheme for agricultural and veterinary chemicals (including funding and cost-recovery arrangements). The APVMA continues to provide input to inform this important policy process.

In addition to the COAG processes, the APVMA has continued to work with policy makers to further improve and refine the National Registration Scheme to align it with contemporary needs and demands. The APVMA has sought to maintain international relationships to produce efficiencies in the delivery of its regulatory functions where possible. The APVMA believes that there are further opportunities to achieve improvements in the efficiency and effectiveness of chemicals regulation. The COAG reform agenda provides a vehicle for such opportunities to be explored and realised.

More information about the Productivity Commission's reviews and chemicals and plastics study can be found on the Commission's website at <http://www.pc.gov.au>. The APVMA's submissions to the Commission are also available from that site.

More information about the COAG chemicals and plastics reform agenda can be found on the COAG website at <http://www.coag.gov.au>.